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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,816	10/02/2003	Gordon Parry	53038AUSM1	3268

7590 03/27/2006
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EXAMINER

MEAH, MOHAMMAD Y

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 03/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/678,816	PARRY ET AL.	
	Examiner	Art Unit	
	Mohammad Meah	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-85 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-85 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

The claims 1-85 are pending in the instant office action.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group 1. Claims 1-2, 5-8, 10-21, 25, 66-69 and 84, drawn hepsin molecules and fragments comprising an amino acid sequence of SEQ ID NO: 1, classified in class 435, and subclass 226.

Group 2. Claims 1-2, 5-8, 10-21, 25, 66-69 and 84, drawn hepsin molecules and fragments comprising an amino acid sequence of SEQ ID NO: 2, classified in class 435, and subclass 226.

Group 3. Claims 1-21, 25, 66-69, 84, drawn hepsin molecules and fragments comprising an amino acid sequence of SEQ ID NO: 3, classified in class 435, and subclass 226.

Group 4. Claims 1-21, 25, 66-69, 84, drawn hepsin molecules and fragments comprising an amino acid sequence of SEQ ID NO: 4, classified in class 435, and subclass 226.

Group 5. Claims 22-24, drawn to method of detecting hepsin cleavage activity in a sample using cleavable substrate by hepsin molecule comprising an amino acid sequence of SEQ ID NO: 1, classified in class 435, and subclass 23.

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Group 6, Claims 22-24, drawn to method of detecting hepsin cleavage activity in a sample using cleavable substrate by hepsin molecule comprising an amino acid sequence of SEQ ID NO: 2, classified in class 435, and subclass 23.

Group 7, Claims 22-24, drawn to method of detecting hepsin cleavage activity in a sample using comprising an amino acid sequence of SEQ ID NO: 3, classified in class 435, and subclass 23.

Group 8, Claims 22-24, drawn to method of detecting hepsin cleavage activity in a sample using cleavable substrate by hepsin molecule comprising an amino acid sequence of SEQ ID NO: 4, classified in class 435, and subclass 23.

Group 9. Claims 26-38, 85, drawn to DNA comprising nucleotide sequence encoding an amino acid sequence of SEQ ID NO: 1, Vector, Host cell, classified in class 435, subclass 252.3.

Group 10. Claims 26-38, 85, drawn to DNA comprising nucleotide sequence encoding an amino acid sequence of SEQ ID NO: 2, Vector, Host cell, classified in class 435, subclass 252.3.

Group 11. Claims 26-39, 85 drawn to DNA comprising nucleotide sequence encoding an amino acid sequence of SEQ ID NO: 3, Vector, Host cell, classified in class 435, subclass 252.3.

Group 12. Claims 26-39, 85, drawn to DNA comprising nucleotide sequence encoding an amino acid sequence of SEQ ID NO: 4, Vector, Host cell, classified in class 435, subclass 252.3.

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Group 13, Claims 40-44, drawn to method of detecting nucleic acid encoding hepsine molecule comprising an amino acid sequence of SEQ ID NO: 1, classified in class 435, and subclass 6.

Group 14, Claims 40-44, drawn to method of detecting nucleic acid encoding hepsin molecule comprising an amino acid sequence of SEQ ID NO: 2, classified in class 435, and subclass 6.

Group 15, Claims 40-44, drawn to method of detecting nucleic acid encoding hepsin molecule comprising an amino acid sequence of SEQ ID NO: 3, classified in class 435, and subclass 6.

Group 16, Claims 40-44, drawn to method of detecting nucleic acid encoding hepsin molecule comprising an amino acid sequence of SEQ ID NO: 4, classified in class 435, and subclass 6.

Group 17, Claims 45-47, 83, drawn to method of producing antibody to hepsin molecule comprising an amino acid sequence of SEQ ID NO:1, classified in class 424 and subclass 185.1.

Group 18, Claims 45-47, 83, drawn to method of producing antibody to hepsin molecule comprising an amino acid sequence of SEQ ID NO:2, classified in class 424 and subclass 185.1.

Group 19, Claims 45-47, 83, drawn to method of producing antibody to hepsin molecule comprising an amino acid sequence of SEQ ID NO:3, classified in class 424 subclass 185.1.

Group 20, Claims 45-47, 83, drawn to method of producing antibody to hepsin molecule comprising an amino acid sequence of SEQ ID NO:4, classified in class 424 and subclass 185.1.

Group 21. Claims 48-65, 67-69, drawn to antibody and kits, which binds to hepsin molecule comprising an amino acid sequence of SEQ ID NO:1, classified in class 530 subclass 387.9.

Group 22. Claims 48-65, 67-69, drawn to antibody and kits, which binds to hepsin molecule comprising an amino acid sequence of SEQ ID NO:2, classified in class 530 subclass 387.9.

Group 23. Claims 48-65, 67-69, drawn to antibody and kits, which binds to hepsin molecule comprising an amino acid sequence of SEQ ID NO: 3, classified in class 530 subclass 387.9.

Group 24. Claims 48-65, 67-69, drawn to antibody and kits, which binds to hepsin molecule comprising an amino acid sequence of SEQ ID NO:4, classified in class 530 subclass 387.9.

Group 25, Claims 70-74, drawn to method of binding hepsin molecule via antibody to protein comprising the amino acid sequence shown in SEQ ID NO:1. classified in class 435 and subclass 23.

Group 26, Claims 70-74, drawn to method of binding hepsin molecule via antibody to protein comprising the amino acid sequence shown in SEQ ID NO:2. classified in class 435 and subclass 23.

Group 27, Claims 70-74, drawn to method of binding hepsin molecule via antibody to protein comprising the amino acid sequence shown in SEQ ID NO:3. classified in class 435 and subclass 23.

Group 28, Claims 70-74, drawn to method of binding hepsin molecule using antibody to protein comprising the amino acid sequence shown in SEQ ID NO:4. classified in class 435 and subclass 23.

Group 29, Claims 75-77, drawn to methods of diagnosis of diseases that express hepsin molecules using antibody to protein comprising amino acid sequence shown in SEQ ID NO: 1. classified in class 435, subclass 7.1.

Group 30, Claims 75-77, drawn to methods of diagnosis of diseases that express hepsin molecules using antibody to protein comprising amino acid sequence shown in SEQ ID NO: 2. classified in class 435, subclass 7.1.

Group 31, Claims 75-77, drawn to methods of diagnosis of diseases that express hepsin molecules using antibody to protein comprising amino acid sequence shown in SEQ ID NO: 3. classified in class 435, subclass 7.1

Group 32, Claims 75-77, drawn to methods of diagnosis of diseases that express hepsin molecules using antibody to protein comprising amino acid sequence shown in SEQ ID NO: 4. classified in class 435, subclass 7.1.

Group 33, Claims 78-82, drawn to methods of treatment of diseases that express hepsin molecules using antibody to protein comprising amino acid sequence shown in SEQ ID NO: 1. classified in class 424, subclass 139.1.

Group 34, Claims 78-82, drawn to methods of treatment of diseases that express hepsin molecules using antibody to protein comprising amino acid sequence shown in SEQ ID NO: 2. classified in class 424, subclass 139.1.

Group 35, Claims 78-82, drawn to methods of treatment of diseases that express hepsin molecules using antibody to protein comprising amino acid sequence shown in SEQ ID NO: 3. classified in class 424, subclass 139.1

Group 36, Claims 78-82, drawn to methods of treatment of diseases that express hepsin molecules using antibody to protein comprising amino acid sequence shown in SEQ ID NO: 4. classified in class 424, subclass 139.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions of groups 1-4 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).). In the instant case, each of group 1-4 inventions involves hepsin polypeptide having unique SEQ ID NO. Each polypeptide having unique SEQ ID NO has distinct structures, properties, function and utilities than that of others.

Inventions in groups 1-4 and 5- 8 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

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different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case hepsin of group 1 can be used for different process such as making antibody of group 17.

Inventions of groups 1-4 and 13-16 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).). In the instant case, proteins of groups 1-4 are neither used nor produced by the methods of groups 13-16.

Inventions in groups 1-4 and 17-20 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case hepsin of group 1 can be used for different process such as in chemical synthesis.

Inventions of groups 1-4 and 25-36 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).). In the instant case, proteins of groups 1-4 are neither used nor produced by the methods of groups 25-36.

Inventions of groups 13-16 and 21-24 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04,

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MPEP § 808.01).). In the instant case, antibody of groups 21-24 is neither used nor produced by the methods of groups 13-16.

Inventions of groups 9-12 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).). In the instant case, each of group 9-12 inventions involves nucleotide having unique SEQ ID NO. Each nucleotide having unique SEQ ID NO has distinct structures, properties, function and utilities than that of others

Inventions of groups 1-4, 9-12, and 21-24 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the invention each set of group of groups 9-12 (DNA), 1-4 (protein) and 21-24 (antibody) involve different compounds having different structures, function and utilities.

Inventions groups 17-20 and groups 21-24 are related as process of making and product made respectively. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case antibody of groups 21-24 can be made other than using the method of groups 17-20, such as chemical synthesis.

Inventions of groups 5-8, 13-16, 17-20, 25-28 and 29-36 are unrelated.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case each methods of groups 5-8, 13-16, 17-20, 25-28 and 29-32 involve different steps involving different products and result different outcomes.

Inventions of groups 9-12, 5-8, 17-20 and 25-36 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).). In the instant case, DNAs of groups 9-12 are neither used nor produced by the methods of groups 5-8, 17-20 and 25-36.

Inventions of groups 21-24 and 5-8 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).). In the instant case, antibodies of groups 21-24 are neither used nor produced by the methods of groups 5-8.

Inventions in groups 9-12 and 13-16 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case DNA of groups 9-12 can be used for different process such as to make protein of groups 1-4.

Inventions in groups 21-24 and 25-28 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case antibody of groups 20-24 can be used for different process such as treating diseases (groups 33-36).

Inventions in groups 20-24 and 29-36 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case antibody of groups 20-24 can be used for different process such as detecting hepsin molecule (groups 25-28).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above

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policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mohammad Meah whose telephone number is 571-272-1261. The examiner can normally be reached on 8:30-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

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information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Mohammad Younus Meah, PhD

Examiner, Art Unit 1652

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